

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Kagan et al.
App. No : 10/698,148
Filed : October 31, 2003
For : APPARATUS AND METHODS FOR
TREATMENT OF MORBID OBESITY
Examiner : Phillip A. Gray
Art Unit : 3767
Conf # : 2819

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicants request a pre-appeal conference panel review of the legal and factual basis of the rejections in the Final Office Action mailed July 9, 2009. No amendments are being filed with this request, and this request is being filed with a Notice of Appeal, along with a request for a three month extension of time.

REASONS FOR REQUEST**Rejections under 35 U.S.C. §§ 103(a)**

In the Final Office Action mailed July 9, 2009, Claims 43-50, 52, 54-61, and 72-73 are rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Pub. No. 2004/0039452 A1 to Bessler in view of U.S. Pat. No. 6,254,642 to Taylor, and further in view of U.S. Pat. No. 5,470,337 to Moss. The aforementioned claims also stand rejected in view of U.S. Pub. No. 2004/0082963 A1 to Gannoe et al. in view of Taylor, and further in view of Moss. Applicants continue to respectfully disagree with the rejections, and review of the above-identified application is requested for the following reasons.

The Examiner has not made a *Prima Facie* Case of Obviousness

Applicants submit that the Examiner has failed to establish a *prima facie* case of obviousness, for the rejections over either Bessler or Gannoe as the primary reference. "The key to supporting any

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rejection under 35 U.S.C. § 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious... [R]ejections on obviousness cannot be sustained with mere conclusory statements." M.P.E.P. § 2142.

Bessler in view of Taylor and Moss

As explained in multiple interviews, previous responses, and the Factual Declaration of Christopher Thompson, M.D. submitted November 21, 2008 of record, Applicants respectfully submit that one of skill in the art would have absolutely no reason to add transmural attachment anchors which are movable from a reduced cross section to an enlarged cross section to the disclosure of Bessler. To the contrary, Bessler teaches a nonpuncturing expanding stent attachment system. By the time of Bessler's filing date, persons skilled in the medical device arts were familiar with a variety of tissue engaging attachment structures such as staples, sutures, and barbs. Yet Bessler failed to disclose any puncturing attachment structures, signaling clear preference for nonpuncturing attachment. Thus, the use of sharpened barbed spikes as disclosed in Taylor or an "H" shaped fastener as disclosed in Moss to secure Bessler's device would be contrary to Bessler's intent of providing a non-penetrating, less traumatic device for gastric bypass. As such, Applicants submit that the Examiner has failed to provide a cognizable reason to combine the references.

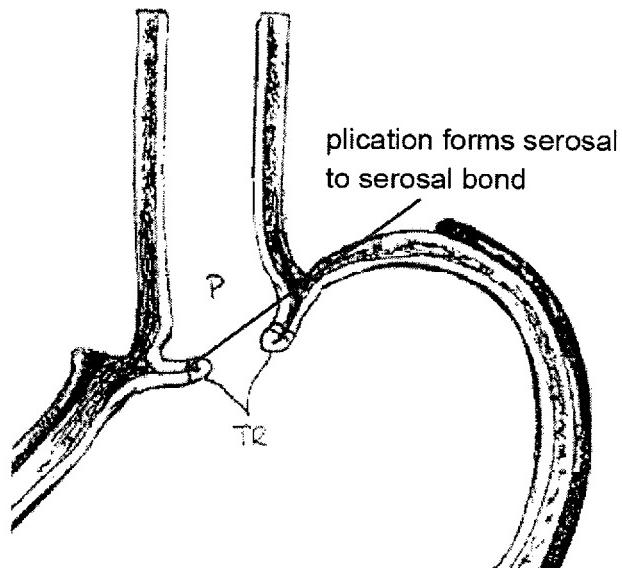
Furthermore, a *prima facie* case of obviousness can only be established if there is a reasonable expectation of success in the combination. M.P.E.P. § 2143.02. As noted in multiple response of record and the aforementioned Thompson Declaration, prior to the present invention, to Applicants' knowledge, all methods of attaching a device to an attachment site near or at the gastroesophageal junction with the exception perhaps of esophageal stents in certain cancer patients, have generally resulted in failure. See Thompson Declaration at para. 9. The Examiner has failed to provide evidence of a reasonable expectation of success in the cited combination, and furthermore has failed to rebut or even acknowledge in any Office Action the substantial evidence provided by Applicants that no reasonable expectation of success exists. For at least the foregoing reasons, Applicants request that the rejection be withdrawn.

Ganno in view of Taylor and Moss

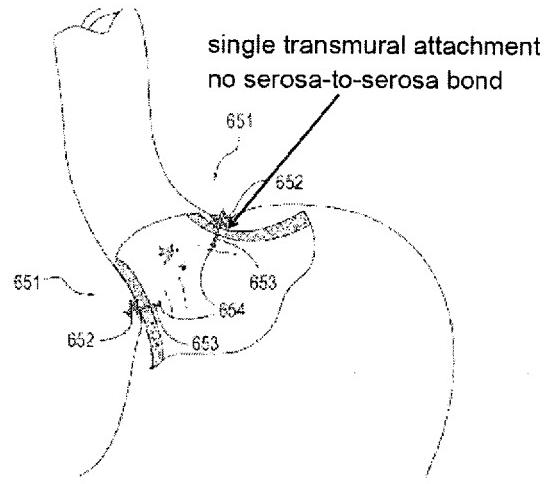
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Ganno discloses methods and devices for creating a tissue ring such as in the upper stomach. As shown in Fig. 5E of Ganno, use of the disclosed device results in acquiring tissue folds in a circumferential configuration within a hollow body organ (Abstract) with mucosal tissue on both external surfaces of the placation, and serosal tissue “sandwiched” in between the mucosal layers. This results in each end of the staple being attached to a mucosal surface of tissue. Attachment of a bypass conduit 113 at the GEJ at the tissue ring, as shown in Fig. 5E of Ganno, results in each end of the staple resting against mucosal tissue of a circumferential tissue fold. Ganno acknowledges the unsolved problem of how to attach a device in the stomach, and proposes as a solution bringing two serosal surfaces in contact with each other across a tissue fold, resulting in a permanent serosa to serosa scar tissue bond to reinforce and hold a tissue plication in place. Because, among other things, the serosa to serosa bond is not easily reversed, Applicants specifically avoid this approach and have expressly excluded this from the present claims.

Even assuming for the sake of argument that Ganno, Taylor, and Moss are combinable, a combination of Ganno, Taylor, and Moss would result in a gastric bypass stent wherein a penetrating attachment is driven through a mucosal-to-mucosal plication as taught by Ganno. Such a combination will still facilitate serosal to serosal bonding via the plication, contrary to the recitation of Claim 43 of “attaching the proximal end [of the gastrointestinal sleeve] at the attachment site without creating a serosal to serosal bond.” Side-by-side illustrations of the serosal-to-serosal bond created by Ganno and an embodiment of the attachment without creating a serosal to serosal bond claimed by Applicants are depicted on the next page. The Examiner has simply failed to identify in the Final Office Action how the proposed combination would create an attachment without creating a serosal to serosal bond as claimed. Since the combination of references fails to teach or suggest each and every claim element, the Examiner has not made a *prima facie* case of obviousness. Furthermore, as noted in M.P.E.P. § 2143.01(V), further modifying the combination (i.e., removing Ganno’s serosal to serosal bond for attachment) would destroy the purpose of Ganno’s device and act as a substantial disincentive for the proposed combination.



Gannoe



Embodiment of claimed method

Secondary Considerations Support a Finding of Non-Obviousness

As noted above, Applicants submit that the Examiner has failed to make a *prima facie* case of obviousness over any of the combinations of references cited as bases for rejection. In addition, Applicants submit that the Examiner has failed to rebut or even acknowledge in any Office Action the substantial evidence of secondary considerations of record, discussed during multiple interviews and previous responses, including the Thompson Declaration of record discussed above.

Secondary considerations must be considered in every case where they are presented. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983); *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007). These include factors such as unexpected results, long-felt need, and failure of others. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1380 (Fed. Cir. 1986); *Graham v. John Deere*, 383 U.S. 1 (1966); *In re Sullivan*, No. 2006-1507 (Fed. Cir. 2007)(holding the PTO is obligated to consider applicant evidence of secondary consideration in cases where obviousness is at issue). A *prima facie* case of obviousness can also be rebutted if the applicant can show that the art in any material respect taught away from the claimed invention. *In re Haruna*, 249 F.3d 1327 (Fed. Cir. 2001).

Teaching Away

As noted in multiple interviews and previous responses, both Bessler and Gannoe teach away from the invention as claimed, and as such are not combinable with the secondary references cited by

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the Examiner. With regard to Bessler, its teachings would lead one of skill in the art in the direction of a non-penetrating anchoring system, such as a balloon expandable or self expanding stent as disclosed therein. Thus, Bessler tends to teach away from the use of a penetrating tissue attachment, and that the use of Taylor's penetrating tissue fastener to secure Bessler's bypass stent would be contrary to Bessler's intent of providing a less traumatic device for gastric bypass. *See* Thompson Declaration at para. 7. With regard to Gannoe, Gannoe's objective of obtaining permanent serosa to serosa healing thus at least implicitly teaches away from the invention as claimed, which excludes serosa to serosa bonding as recited in Claim 43. *See* Thompson Declaration at para. 8.

Failure of Others/Unexpected Results

As noted above, prior to the present invention, to Applicants' knowledge, all methods of attaching a device to an attachment site near or at the gastroesophageal junction with the exception perhaps of esophageal stents in certain cancer patients, have generally resulted in failure. *See* Thompson Declaration at para. 9. These methods have experienced a myriad of problems such as, for example, anchor migration, wall erosion, or rupture resulting in undesired device placement or explantation. *Id.* Applicants submit that one of ordinary skill in the art would be concerned that attempts to modify such devices would render them difficult or dangerous to remove from the gastrointestinal tract, and in fact it was unexpected that the claimed methods have been very effective in stably and securely attaching a device to an attachment site near the gastroesophageal junction, as evidenced by both animal and human trials performed thus far. *Id.*

In short, Applicants' surprising success in achieving attachment without substantial modification to the native tissue in the vicinity of the gastroesophageal junction was completely unpredictable to those of skill in the art familiar with the prior art references applied herein. I

In conclusion, Applicants submit that the application is in condition for allowance.

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Dated: 11/11/10

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